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<b>REPLY BRIEF</b>  Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application No.	10/029,408
	Confirmation No.	3760
	Attorney Docket No.	CALD-005
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	First Named Inventor	CALDWELL, LARRY
	Examiner	VU, JAKE MINH
	Group Art	1618
	Title: "METHODS AND COMPOSITIONS FOR TREATING CARPAL TUNNEL SYNDROME "	

Sir:

This Reply Brief is filed in response to the Examiner's Answer mailed by the Office on December 11, 2008, making this Reply Brief due by February 11, 2009.

The Commissioner is hereby authorized to charge any fees or provide any relief that may be required, or to credit any overpayment, to deposit account number 50-0815, reference no. CALD-005.

### REPLY BRIEF

In this Reply Brief, the Appellants address issues raised in the Examiner's Answer. The Appellants note that all arguments presented in the Appeal Brief still apply with equal force, but are not reiterated here solely in the interest of brevity and for the convenience of the Board.

*Group I: Claims 1-3, 5-8, 10-12, 14-18 and 35*

In the Appellant's Brief, Appellants argued that Bockow in view of Edwards fails to render the claimed invention obvious because 1) there is no apparent reason to combine teachings of Bockow and Edwards as asserted by the Examiner based on the background knowledge in the art; and 2) one of skill in the art could not have predicted success in practicing the claimed invention.

To support the first argument that there is no apparent reason to combine teachings of Bockow and Edwards, Appellants provided excerpts of a scientific article and the declarations of record in the present application. These excerpts constitute background knowledge that would have been possessed by one of ordinary skill in the art at the time of the invention. Based on the background knowledge of one of ordinary skill in the art (as evidenced by scientific articles and declarations of record in this application), Appellants demonstrated why one of ordinary skill in the art would not have read Bockow as teaching a method for treating CTS and thus would actually not combine the two references to use Bockow's formulation in Edward's method.

In response, the Examiner continues to discount the Appellants' position stating, "because BOCKOW explicitly disclosed treating CTS (see col. 6, line 61-62); thus one in the art would have read BOCKOW as teaching a method for treating CTS." See Examiner's Answer, page 14, first ¶.

Appellants submit that the Examiner has no reason to ignore the statements in the declarations of record and must accept that one of ordinary skill in the art would not have read Bockow as teaching a method for treating CTS in view of the evidence provided.

Throughout the Examiner's Answer, the Examiner does not provide any reasoning as to why the evidence was insufficient to overcome the teachings of Bockow. Indeed, the Examiner does not indicate whether the evidence has even been considered. As such, the Examiner appears to view the declarations and evidence of record as unsubstantiated evidence that is not given any weight.

As set out below in MPEP §716.01 (c), opinion testimony that is not on the ultimate legal conclusion at issue should be given some weight.

Although factual evidence is preferable to opinion testimony, such testimony is entitled to consideration and some weight so long as the opinion is not on the ultimate legal conclusion at issue.

Appellants wish to direct the Examiner's attention to the following declarations of record.

- The 1.132 declaration filed June 5, 2006, in which Bradley Galer, M.D. states that CTS, when compared to musculoskeletal disorders, has symptoms arising from a completely different system and thus one would approach the treatment differently, as evidenced by Exhibits A-D including excerpts from Classification of Chronic Pain and Evidence-Based Management of Acute Musculoskeletal Pain, and Finnerup et al. *Pain* 118:289-290; and
- The 1.132 declaration filed May 9, 2007, in which Bradley Galer, M.D. states that CTS and musculoskeletal disorders have entirely distinct pathologies, symptomologies, different diagnostic testings, and different modes of pharmacological actions, as evidenced by Exhibits A-J including excerpts of scientific books, printouts of websites, and scientific journal articles in the art.

The declarant, Dr. Galer, is qualified to opine on what one of ordinary skill in the art would believe regarding a given reference. His declaration is not submitted as to the ultimate legal conclusion at issue, i.e., obviousness. Rather it is submitted with exhibits comprising scientific journal articles and excerpts of scientific books to establish what background knowledge a reasonably skilled practitioner in the art would have possessed at the time of the invention. Furthermore, the declarations by Dr. Galer agree with the statements in the scientific article by Dieleman, the excerpts of which were reproduced in the Appeal Brief (Dieleman *et al.*, Incidence rates and treatment of neuropathic pain conditions in the general population, *Pain* 137:681–688 (31 July 2008)).

As such, there is no reason why the Examiner should not accord any weight to the evidence submitted by Appellants in determining whether one of ordinary skill in the art would have read Bockow as teaching a method for treating CTS.

The declarations clearly demonstrate that one of ordinary skill in the art would read Bockow's disclosure as limited to the treatment of musculoskeletal disorders and that one of ordinary skill in the art would not consider CTS to be a musculoskeletal disorder.

Furthermore, nothing in Bockow negates the statements of Dr. Galer and Dr. Caldwell.

In the Examiner's Answer, the Examiner cites Petrus (US 6,399,093) as evidence that others of ordinary skill in the art have characterized CTS as musculoskeletal disorders (§ bridging pages 14 and 15).

Contrary to the Examiner's understanding, the only mention of CTS in Petrus appears in the background section of this patent. Furthermore, the mention of CTS is not in the context of CTS being an example of a musculoskeletal disorder. As reproduced

below, Petrus refers to CTS as a type of occupational hazard, not as a musculoskeletal disorder (col. 1, lines 27-43, emphasis added).

Occupational injuries however, have become this country's most costly form of illnesses. The Bureau of Labor Statistics reported in 1992, that one half of the 2.3 million nonfatal occupational injuries and illnesses which resulted in days away from work involved musculoskeletal disorders. The Occupational Safety and Health Administration (OSHA) estimates in 1999, that more than 647,000 Americans suffer from injuries or illnesses due to work-related musculoskeletal disorders (WMSDs). These disorders account for more than 34% of all workdays lost to injuries and illnesses and cost employers \$15 to \$20 billion per year in direct workers' compensation costs and another \$100 billion on lost productivity, employee turnover, and other indirect expenses. Cumulative trauma disorders (CTDs) frequently involve the upper extremities, such as wrists, shoulders or elbows. Carpal tunnel syndrome of the wrist has become the fastest growing occupational hazard in the United States today.

Furthermore, the very next line of Petrus reads (col. 1, lines 45-46):

Arthritis, a musculoskeletal disorder, is the leading cause  
of disability in the United States. The Centers for Disease

As such, if Petrus actually viewed CTS as a type of musculoskeletal disorder, Petrus would have clearly referred to it as such. Accordingly, Petrus does not evidence that others of ordinary skill have characterized CTS as musculoskeletal disorders.

Consequently, the Examiner has not provided any evidence sufficient to negate the declarants' statements.

Because the evidence provided by Appellants outweighs Bockow's disclosure of CTS as a musculoskeletal disorder, one of ordinary skill in the art would not read Bockow as teaching a method for treating CTS. Thus, the skilled artisan would not combine the two references to use Bockow's formulation in Edward's method.

Accordingly, there is no apparent reason to combine Bockow with Edwards as the Examiner has done in making this rejection and this rejection may be reversed for this reason alone.

Additionally, in the Appellant's Brief, to support the second argument that one of ordinary skill in the art could not have predicted success in the claimed invention based on teachings of the prior art references, Appellants provided excerpts of the declarations of record in the present application. Based on the background knowledge as evidenced in the declarations, Appellants demonstrated why one of ordinary skill in the art would not have predicted success in the effective delivery of an NSAID formulation to the median nerve inside the carpal tunnel upon topical application to a palmar dermis or in treating CTS with an NSAID formulation, upon reading Bockow.

In response, the Examiner continues to discount the Appellants' position stating, "because BOCKOW explicitly disclosed treating CTS (see col. 6, line 61-62); thus one skilled in the art would have a reasonable expectation of success." See Examiner's Answer, page 15, second ¶.

As in his response to Appellants' first argument, the Examiner appears to view the declarations and evidence of record as unsubstantiated evidence that is not given any weight.

Appellants wish to direct the Examiner's attention to the 1.132 declaration filed April 26, 2004, in which Larry Caldwell, Ph.D. states that (1) just because an active agent is administered topically to treat one condition does not mean that it can be effective when topically administered to treat other conditions and this is particularly true if the sites of topical application differ; and (2) because of the location of the target nerves which are responsible for carpal tunnel syndrome, it was not at all certain that the claimed

methods would work prior to the actual reduction to practice reported in the application.

Dr. Caldwell is qualified to provide factual evidence in the art and opine on what one of ordinary skill in the art would believe based on the factual evidence. His declaration is not submitted as to the ultimate legal conclusion at issue, i.e., obviousness. Rather, the declaration provides factual evidence.

As such, there is no reason why the Examiner should not accord any weight to the evidence submitted by Appellants in determining whether one of ordinary skill in the art would have a reasonable expectation of success in the claimed invention; nor does the Examiner provide evidence sufficient to negate the declarants' statements.

The declaration provides factual evidence to support the reason that one of ordinary skill in the art would need to perform actual experiments and subsequently obtain positive results showing that an NSAID formulation, when applied to the palmar dermis, would cross tendons, blood vessels and especially a bone or a thickened sheath to reach the median nerve of the carpal tunnel, before one of ordinary skill in the art would have a reasonable expectation of success in the claimed invention.

Bockow is completely silent on this issue of delivery of an NSAID formulation to the carpal tunnel and provides no relevant data of suce.

Therefore, one of skill in the art could not have predicted success in practicing the claimed invention prior to the Appellants' work reported in the present application.

In light of the above analysis, there is no apparent reason to combine teachings of Bockow and Edwards as asserted by the Examiner and one of ordinary skill in the art could not have predicted success in practicing the claimed invention based on the teachings of the cited prior art references. Accordingly, the claims of Group I are not

obvious under 35 U.S.C. §103(a) over Bockow in view of Edwards and this rejection should be reversed.

*Group X: Claim 33*

In the Appellant's Brief, Appellants argued that the combination of the cited references fails to teach or suggest two elements of the claims – 1) a hydrogel adhesive and 2) a polyester felt backing.

In the Examiner's Answer, the Examiner asserts that Liebschutz teaches a polyester felt backing (§ bridging pages 25-26). In neither in the Examiner's Answer nor the Final Office Action does the Examiner mention that any of the cited references teach a hydrogel adhesive.

In fact, as detailed in the Appellants' Brief, none of the cited references teach or suggest the claimed element of a hydrogel adhesive.

As such, the Examiner failed to establish *prima facie* obviousness. Accordingly, the Appellants submit that the combination of cited references does not render the claim of Group X obvious under 35 U.S.C. § 103. Accordingly, the reversal of this rejection is respectfully requested.

*Group XI: Claim 40*

In the Appellant's Brief, Appellants argued that the combination of the cited references fails to teach or suggest that the NSAID is the only active agent of the topical NSAID formulation.

In the Examiner's Answer, the Examiner asserts that the transitional term "comprise" indicates inclusion of other ingredients (page 26, ¶ 2). As such, the Examiner appears to believe that the combination of the cited references does not need to teach



or suggest the claimed element of NSAID as the only active agent in establishing *prima facie* obviousness.

Appellants respectfully disagree and submit that the Examiner failed to make a *prima facie* case of obviousness because the Examiner did not find all the elements taught or suggested in the cited references.

With respect to the transitional term “comprising,” the Federal Court stated that “the earlier term ‘comprising’ means that the claim can include that portion plus other nucleotides.” *In re Crish*, 73 USPQ 2d 1364, 1367 (Fed. Cir. 2004). As such, the Examiner must still show the claimed element taught or suggested in the prior art.

Because the Examiner failed to point out that the cited references teach or suggest a topical NSAID formulation in which NSAID is the only active agent, *prima facie* obviousness has not been established.

In fact, as argued in the Appellant’s Brief, Bockow teaches away from the claimed element because Bockow’s formulation requires the presence of an omega fatty acid and spirulina, both as active agents. Consequently, Claim 40 is additionally distinguished over Bockow in view of Liebschutz. Accordingly, the rejection of Claim 40 should be reversed.

**CONCLUSION**

The Appellants respectfully request that all rejections of Claims 1-19 and 24-40 under 35 U.S.C. §103 (a) be reversed and that the application be remanded to the Examiner with instructions to issue a Notice of Allowance.

Respectfully submitted,

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